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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,771	06/20/2003	Jessica E. LeMay	460.2174USU	7298

7590 04/20/2006

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EXAMINER

HILL, LAURA C

ART UNIT PAPER NUMBER

3761

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/601,771

Applicant(s)

LEMAY ET AL.

Examiner

Laura C. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

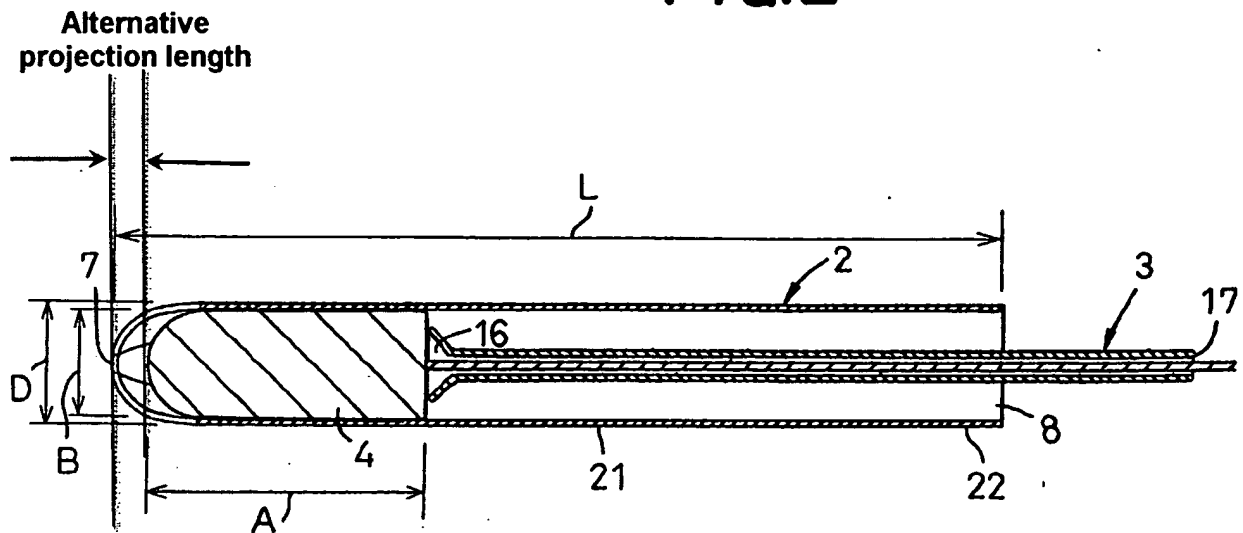
- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 15 February 2006 have been fully considered but they are not persuasive.

In response to Applicant's arguments that 'the taper ratio that is equal to a tapered length A divided by a barrel radius identified by reference letter D of Suga is not equal to a taper ratio that is a length of a projection of the insertion tip taper along a longitudinal axis of the barrel to a length of a projection of the insertion tip taper along a radius of the barrel at a base region of the one or more of petals, as provided in claims 1 and 37' (see Remarks page 15), Applicant discloses the 'projection length' to be represented by line CD (see page 5, lines 15-19 of the instant Specification). Therefore, the Examiner maintains that tampon length A is equivalent to length of projection of the insertion as discussed on page 3 of the Office action dated 16 November 2005. Furthermore, assuming *arguendo* that the taper projection length defined by Applicant is not equivalent to the tampon length A of Sugar, the taper ratio will still fall in the range of 'greater than 1 to about 8' as required by Applicant since the 'taper projection length' could also be the distance between the outermost end of the tampon and outermost dome portion adjacent petals 7 in annotated figure 2 below. If the 'taper projection length' was defined as suggested by Applicant, this length would be some value less than the tampon length A and therefore the taper ratio would still fall in the Applicant's claimed range of 'greater than 1 to about 8'.

FIG.2

In response to Applicant's arguments that 'Suga merely provides that diameter D is in a range between 8-20 mm and does not disclose or suggest tapering of any kind' (see Remarks page 15), Suga discloses the taper ratio range as discussed above and below with respect to claim 1 and thus discloses a tapering that is correlated with the taper ratio.

In response to Applicant's piecemeal analysis of the references (i.e. Suga fails to disclose a plurality of petals that each have a thickness of about 0.004 inches to about 0.022 inches with a substantially uniform thickness as per Remarks pages 15-16), it has been held that one cannot show non-obviousness by attacking references individually where, as here, the rejections are based on combinations of references. *In re Keller*, 208 USPQ 871 (CCPA 1981). Examiner maintains that Suga is not relied upon for teaching the petal thickness and uniformity but rather Berger is relied upon for these teachings as discussed on page 3 of the Office action dated 16 November 2005.

In response to Applicant's arguments that Suga and Berger alone or in combination fail to disclose all of the claimed features recited in claim 72 and that there should be a withdrawal of the rejection of all dependent claims (see Remarks pages 17-18), see the discussion above with respect to Applicant's arguments against both of these references and also see the previous Office action dated 16 November 2005.

In response to Applicant's piecemeal analysis of the references (i.e. Werner fails to disclose a plurality of petals that have a substantially uniform thickness as per Remarks page 18), it has been held that one cannot show non-obviousness by attacking references individually where, as here, the rejections are based on combinations of references. *In re Keller*, 208 USPQ 871 (CCPA 1981). Examiner maintains that Werner is not relied upon for teaching the petal thickness but rather for teaching barrel taper ratio as discussed on page 6 of the previous Office action dated 16 November 2005.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-6, 8-10, 13-22, 32-61, 63-64 and 66-73 are rejected under 35 U.S.C. 103(a) as being obvious over Suga (US 2001/0056253; herein 'Suga') in view of Berger et al. (US 3,895,634; herein 'Berger'). Regarding claims 1-6 Suga discloses tampon applicator comprising a barrel 2 having a tapered insertion end having two petals and a taper ratio of 3-4

[taper projection length = tapered tampon length A = 20-60 mm;

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therefore taper ratio= tapered length A/barrel radius D=

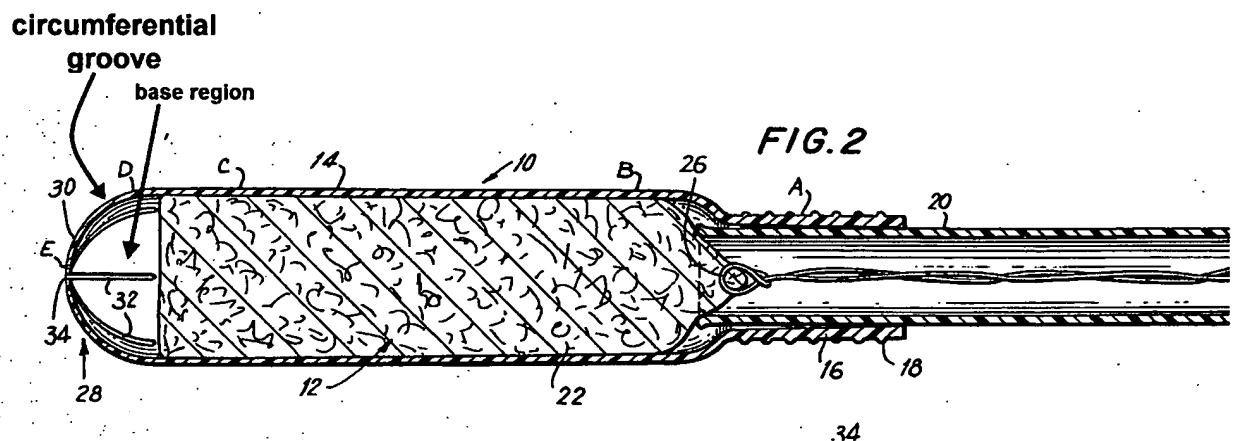
= 20/8 to 60/20=3-4 (figure 2, paragraph 0011, lines 9-19).

Suga *does not expressly disclose* a petal thickness. **Berger** discloses a tampon inserter 10 with a front barrel member 14, which tapers at its rear end and having a plurality of triangular segments/petals 30 (col. 5, ll. 9-11, figure 1). Berger further discloses the cross-sectional thickness of the petals will be at least 0.005 inch and most preferably at least 0.0075 inch that is less than the mean cross-sectional thickness of the cylindrical portion of front barrel member 14 (col. 7, ll. 19-23). Berger further discloses substantially uniform petal thickness (figures 1 and 4). One would be motivated to modify the petals of Suga with the uniform petal thickness of Berger to provide an easily-inserted apparatus since both references are in the same field of endeavor; tampon applicators with a tapered barrel and a plurality of petals. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the petals, thus providing the claimed petal thickness.

Alternatively, taper ratio and petal thickness are result effective variables since they are a result of the overall tampon applicator size and the thickness/diameter of the tampon applicator. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify Suga/Berger with taper ratio and petal thickness values, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch and Slaney*, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claims 8-10 Suga/Berger *do not expressly disclose* the petal thickness varies in the claimed values. Petal thickness variation is a result effective variable since it is at least a result of the tampon applicator thickness. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Suga/Berger with petal thickness variation values, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch and Slaney*, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claims 13-22 Berger further discloses a finger grip 16, the area, which contains a plurality of circumferentially, disposed depressed treads/ribs 18 (col. 5, ll. 9-14 and figures 1 and 2) and a plurality of triangular segments/petals 30 that are separated by space/radial slit 32 between the segments/petals and extending below a base region, said base region having a circumferential groove on the outer wall (col. 5, ll. 35-38, figures 1, 2 and 4).



Regarding claim 32 Suga/Berger disclose a tampon applicator with two petals as discussed above with respect to claim 19. Berger et al. further discloses weakened tip/base region 34 that is rounded to reduce the possibility of segments/petals 30

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overlapping at their juncture to prevent possible scratching of vaginal tissue during use (col. 5, ll. 38-41). The method of forming the device (i.e.: 'formed by bending said petals back and forth, thereby breaking one or more bonds') is not germane to the issue of patentability of the device itself. Therefore, this limitation has been given little patentable weight.

Regarding claims 33-36 Berger further discloses the tampon inserter is formed from cardboard or polyolefins such as polyethylene (column 6, lines 36-45).

Regarding claim 37 see the discussion above with respect to claims 1 and 33.

Regarding claims 38-42 see the discussion above with respect to claims 1 and 2-6.

Regarding claims 43-50 see the discussion above with respect to claims 1 and 7-14.

Regarding claims 51-60 see the discussion above with respect to claims 1 and 15-24.

Regarding claims 61, 63-64 and 66-73 S see the discussion above with respect to claims 1, 12 and 25-37.

2. Claims 11-12, 23-31, 62, 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suga (US 2001/0056253; herein 'Suga') in view of Berger et al. (US 3,895,634; herein 'Berger') as applied to claim 1, and in further view of Werner et al. (US 3,765,416; herein 'Werner'). Suga/Berger *do not expressly disclose* a ratio of extension, slit to groove ratio, barrel maximum outside diameter values. **Werner** discloses tampon 24 encased in plastic tube/barrel 26 having a tapered insertion end

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with triangular segments/petals 28 (col. 4, ll. 39-42, figures 4 and 5). Werner further discloses a barrel taper ratio of the largest outside barrel radius A to a radius at the base of insertion end B of 1.04 [$A/B=0.579 \text{ inch}/0.556 \text{ inch}$] (col. 3, ll. 30-34). One would be motivated to modify the barrel of Suga/Berger with the barrel taper ratio of Werner for improved insertion since the references are in the same field of endeavor; disposable tampon applicators with tapered ends and petals. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the barrel and thus providing a barrel taper ratio.

Alternatively, barrel taper ratio, ratio of extension, slit to groove ratio, barrel maximum outside diameter are result effective variables since they are at least a result of the overall applicator barrel size. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to It would have been obvious to one having ordinary skill in the art at the time the invention was made to Suga/Berger/Werner with the aforementioned values, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch and Slaney*, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (off every other Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura C. Hill
Examiner
Art Unit 3761
LCH



TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER





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APPLICATION NO/ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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10-601-771

EXAMINER

ART UNIT

PAPER

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DATE MAILED:

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Commissioner for Patents